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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,176	07/12/2004	George A. Doherty	21014YP	7849

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	
ART UNIT	**PAPER NUMBER**
1609	
MAIL DATE	**DELIVERY MODE**
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,176	DOHERTY ET AL.	
	Examiner	Art Unit	
	Samira Jean-Louis	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I, claims 1-22, 46-59 are drawn to a method for treating an immunoregulatory abnormality comprising administering to said patient a compound which is an agonist of the $S1P_1$/Edg1 receptor.

II. Group II, claims 23-24 are drawn to a pharmaceutical composition comprised of a compound, which is an agonist of the $S1P_1$/Edg1 receptor.

III. Group III, claims 25-45 are drawn to a method of identifying a candidate compound, which is an agonist of the $S1P_1$/Edg1 receptor.

IV. Group IV, claim 60 is drawn to a method of reducing or preventing the activation of the $S1P_1$/Edg1 receptor.

V. Group V, claim 61 is drawn to a method of inhibiting an infiltration of a lymphocyte into a respiratory tissue in a mammalian patient in need thereof.

The inventions listed as Groups I, II, III, IV, and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings. Whether or not any specific technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature", should be considered with respect to novelty and inventive step.

In group I of this instant application, the special technical feature lies in treating an immunoregulatory abnormality which involves the immune system in some capacity.

In group II of this instant application, the special technical feature lies in the composition exemplified by various compounds (see Specification, pgs. 13-27).

In group III of this instant application, the special technical feature lies in identifying a candidate compound and this process may or may not entail the compounds of group II.

In group IV of this instant application, the special technical feature lies in inhibiting the activation of the $S1P_1$ receptor, which does not require the use of said agonist.

Finally, in Group V of this instant application, the special technical feature lies in the inhibition of an infiltration of a lymphocyte into a respiratory tissue. Again, this special technical feature does not necessarily require the use of said composition of group II.

Therefore, in this instant application, the technical features in all groups are different. Consequently, these various special technical features cannot be said to be a common special technical feature under PCT Rule 13.2 because there is no shared special technical relationship among those inventions.

As a result, no special technical features exist among the different groups because the inventions in Groups I, II, III, IV, and V fail to form a single general inventive concept. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to more than one species of the generic invention. These species either possess divergent structures and/or materially different functions (i.e. compounds for treating multiple sclerosis vs. pneumonia) or treatments pertain to different types of tissues (i.e. multiple sclerosis involves nervous system while pneumonia will involve epithelial tissue. Thus, these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species listed below do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same special technical feature among the different species.

The species are as follows:

1) ***for Group I-V***:

a) applicant is required to elect a particular compound out of the list in the specification section, pg. 13-27.

2) also ***for Group I***

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a) applicant is required to elect a particular type of immunoregulatory abnormality as listed in claims 12-22.

b) applicant is required to elect a particular respiratory disease or condition out of the list in claim 57.

c) applicant is required to state if the method of treating a respiratory disease or condition will further entail concomitant or sequential administration of agents. In the event that additional agents will be included, applicant is further required to elect a particular agent out of the list in claim 58.

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3) also ***for Group III***:

a) applicant is required to elect a recombinant cell to be used with said method out of the list in the specification section, pg 156, lines 17-21.

b) applicant is further required to state if said method of identifying a compound will or will not entail conducting said method in the presence of labeled S1P, unlabeled S1P or a ligand and if said method will or will not comprise measuring a signal. In the event, applicant elects to conduct said method in such manner, applicant is further required to elect a particular species out the listed group (i.e. labeled S1P, unlabeled S1P or a ligand) in claim 26.

c) Furthermore, applicant is required to also elect a particular signal out of claims 38-41.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claims 1-61 are generic.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SJL

08/17/07

8/18/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER